1824 South Robertson Blvd. Les Angeles, CA 90035-4317 310/204-6936 • 800/726-0886 www.Jarrow.com FAX NUMBERS
Orders 800/890-8955
General 310/204-2520
Administrative 310/204-5132

May 28, 2003

Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Nutritional Products, Labeling, and Dietary Supplements (HFS-810)
5100 Paint Branch Parkway
College Park, Maryland 20740
Reference phone #301-436-2373



#### Dear CFSAN:

Pursuant to Section 403(r)(6) of the Federal Food, Drug and Cosmetic Act and Section of 101.93 of FDA's regulations, we hereby notify you that we are using the following statement(s):

### (1) Name of Address of distributor:

Jarrow Formulas, 1824 South Robertson Blvd., Los Angeles, CA 90035

### (2) Text of the statement(s):

MiBrain™ is a blend of standardized herbal extracts combined with magnesium, chromium, vitamin B2 and Omega 3 fatty acids for optimum brain function.

- MaxDHA is a source of Omega 3-fatty acids known to generate prostaglandins series 3 (PGE3) and support brain function.
- Butterbur contains petasine and isopetasine which may reduce the formation of leukotrienes and improve neurocirculation. Devil's Claw contains harpagosides (iridoid glycosides) which are natural COX-2 inhibitors. White Willow Bark is a bitter herb rich in flavonoids and salicyclic derivatives (salicin and salicortin) responsible for inhibiting COX-2.
- Other MiBrain™ Herbs: Feverfew, Green Tea, and Ginger are sources of powerful phenolic antioxidants which support healthy circulation and brain metabolism.
- Magnesium supports healthy platelet metabolism and circulation. Vitamin B2 is added to support mitochondrial energetics in the brain. Chromium is an essential mineral micronutrient involved in the metabolism of carbohydrates.

# (3) Name of the dietary ingredient(s) if not provided in the text of the statement:

Vitamin B2 (Riboflavin) • Magnesium (as Citrate/Oxide 50/50) • Chromium (from Saccharomyces cerevisiae) • Omega 3 Fatty Acids (from Sardine Oil) (Providing 125 mg DHA and 50 mg EPA) • Feverfew (Tanacetum parthenium) • Butterbur (Petasites hybridus)(30:1 extract) • Ginger (Zingiber officinale) (rhizome)(5% Gingerols and Shogaols) • Devil's Claw (Harpagophytum procumbens)(5% Iridoid Glycosides) • White Willow Bark (Salicis cortex)(15% Salicin) • Green Tea (Camellia sinensis)(60% Polyphenols)

### (4) Name of the dietary supplement(s)

MiBrain<sup>TM</sup>

120 softgels

LET 12298

## (5) The following disclaimer appears on the label in bold:

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

These claims are limited to, and a result of, what we believe to be a substantial body of scientific evidence supporting the functional role of these nutrients.

Respectfully submitted,

Siddharth Shastri

Vice President, Product Development